DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 02D–0073]

"Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation" dated March 2002. The guidance document is intended to remind all tissue establishments that the current requirement to prepare, validate, and follow procedures to prevent infectious disease contamination or cross-contamination during the processing of human tissues intended for transplantation includes such infectious disease agents as viruses, bacteria, fungi, and will include transmissible spongiform encephalopathy (TSE)-associated prions as technology progresses.

DATES: General comments on agency guidance documents are welcome at any time. The agency is soliciting public comment, but is implementing this guidance document immediately because of public health concerns. FDA is requesting that you submit with your comments any information on specific methods currently used by tissue establishments to prevent infectious disease contamination and cross-contamination of tissue during processing.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your

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requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.Submit written or electronic comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation" dated March 2002. The document is intended to remind all tissue establishments that the current requirement to prepare, validate, and follow procedures to prevent infectious disease contamination or cross-contamination during the processing of human tissues intended for transplantation (21 CFR 1270.31(d)) includes such infectious disease agents as viruses, bacteria, fungi, and will include TSE-associated prions as technology progresses. Current regulations for human tissue intended for transplantation are found in 21 CFR parts 1270 and 1271.

This guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the validation of procedures for processing of human tissues intended for transplantation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of infectious disease contamination or cross-contamination during tissue processing. In particular, FDA's concern is heightened by recent reports from the Centers for Disease Control and Prevention about bacterial contamination of musculoskeletal allografts associated with injury as well as death in recipients of these tissues [MMWR; 50(46): 1035–1036, November 23, 2001; 50(48): 1080–1083, December 7, 2001.] FDA is requesting that you submit with your comments any information on specific methods currently used by tissue establishments to prevent infectious disease contamination and cross-contamination of tissue during processing. FDA plans to have further public discussion on this issue and to develop additional guidance containing more specific recommendations on validation methods for tissues in the future.

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 3/4/2

March 4, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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